

Notice of Allowability

Application No.

09/740,191

Examiner

Humera N. Sheikh

Applicant(s)

DONG ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03 January 2006.
2. ☒ The allowed claim(s) is/are 12-15 and 25.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The drawings filed 12/19/00 are accepted by the Examiner.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 03/28/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, Applicant's Arguments/Remarks and the request for extension of time (2 months-granted), all filed 01/03/06 is acknowledged.

Claims 12-15 and 25 are pending in this action. Claims 1-11 and 16-24 have been cancelled. Claims 12-15 and 25 are allowed.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Adenike A. Adebiyi on March 28, 2006.

The application has been amended as follows:

In the Specification:

In the 'Reference to Related Applications' section, after the term 'now US Patent No.', the term '**6,174,547**' has been **added**.

In the Claims:

In claim **12**, line 6, after the terms '*an oil*', the following has been added: **"wherein the oil is selected from the group consisting of a vegetable, mineral, animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid, oleylester, glycolyzed ethoxylated glycerides of oils, fatty acids comprising 13 molecules of ethyleneoxide, and oleic acid decylester"**.

In claim **12**, last line, after the term '*capsule*', the following has been added:
"wherein the semipermeable membrane comprises a thermoplastic polymer composition having a softening point of 40°C to 180°C".

Claims **18** and **24** have been **cancelled**.

In the Abstract:

A new Abstract has been provided, wherein the term '*said*' has been replaced with the term **"the"**.

Allowable Subject Matter

Claims 12-15 and 25 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Wong *et al.* – U.S. Patent No. 5,324,280 & Lambert *et al.* – U.S. Patent No. 6,458,373 B1) does not disclose nor suggest or teach the instant sustained release dosage form for the delivery of a progestogenic steroid, wherein the dosage form comprises at least the following components: a self-emulsifying drug formulation contained within a first portion of the capsule; an expandable layer contained within a second portion of the capsule; and a semi-permeable membrane that is formed over at least a portion of an outer surface of the capsule, whereby the semi-permeable membrane comprises a thermoplastic polymer composition having a softening point of 40°C to 180°C”.

In contrast, the prior art (Wong *et al.* '280) teach an osmotic dosage form wherein a drug formulation is contained within a capsule. The capsule itself is encapsulated within a hydro-activated layer (or expandable layer). This is in stark contrast to the invention recited in claim 12 wherein the expandable layer is contained within the capsule. Wong *et al.* fail to disclose or teach locating an expandable layer and a self-emulsifying progestogenic steroid formulation within the same capsule. The teachings of Wong *et al.* are the opposite of the instantly claimed invention since Wong *et al.* teach that their liquid formulation is initially essentially free of direct contact with a hydro-activated expansion composition. The prior art provides no motivation or suggestion to employ an expandable layer and a self-emulsifying progestogenic steroid formulation within the same capsule. Lambert *et al.* ('373) teach a α -tocopherol emulsion in the

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form of a self-emulsifying system encapsulated in a soft or hard gelatin capsule. Lambert *et al.* do not disclose or teach that an expandable layer is contained within the capsule that contains the emulsion. Thus, the prior art, either alone or in combination, fails to meet the limitations of the instant invention.

The instant invention demonstrates an improvement over prior art formulations because it provides for a dosage form comprising a liquid formulation comprising a drug that can self-emulsify to enhance the solubility, the dissolution and the bioavailability of the drug. The self-emulsifying drug formulation can also prevent drug particles from aggregation or agglomeration during storage and drug delivery over time. The instant invention can also avoid possible erratic drug release profile and high amounts of drug residue after release, which would likely occur using prior art formulations.

In the telephonic interview held 03/28/06 between Attorney of record and myself, suggestions were made by the Examiner to incorporate the claim limitations of claims 18 and 24 into independent claim 12, which would place the instant application in condition for allowance. Attorney adopted the Examiner's suggestion, thereby rendering the instant application non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

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March 30, 2006


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